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Application Number 10647068

Filing Date 2003-08-22

First Named Inventor Argenta, et al.

Art Unit 3733

Examiner Name PHILOGENE, PEDRO

Attorney Docket Number 0101-P02977US1

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1	ARGENTA, A., et al., "Deformation of superficial and deep abdominal tissues with application of a controlled vacuum", European Tissue Repair Society, Focus group meeting Topical Negative Pressure (TNP) Therapy, London UK (4–6 December 2003). WFU-55	
2	ARGENTA, L., et al., "Vacuum assisted closure (VAC therapy) for secondary closure of dehisced and infected wounds", Wound Repair and Regeneration, (July-September, 1995), pp. 361; 5th Annual Meeting of the European Tissue Repair Society, Padova Italy, (1 page of abstract) (August 30-September 2, 1995). WFU-11	
3	ARGENTA, L.C., et al., "Use of V.A.C. for treatment of dehisced sternal incisions", Plastic Surgical Forum, vol. XXIII, 69th Annual Scientific Meeting of the American Society of Plastic Surgeons, Los Angeles, CA, pp. 172-174. (2 sheets of abstract.) (October 14-18, 2000). WFU-06	
4	ARGENTA, L.C., et al., "The V.A.C. as an adjunct for treatment for abdominal wounds", 66th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, San Francisco, CA, pp. 330-331; 1 sheet of abstract (September 21-24 1997). WFU-39	
5	ARGENTA, L.C., et al., "Vacuum assisted closure of chronic wounds", 65th Annual Scientific Meeting, American Society of Plastic and Reconstructive Surgeons, Dallas, TX, pp. 226-227; 1 sheet of abstract (November 9-13, 1996). WFU-37	
6	BANWELL, P., et al. eds., "Topical Negative Pressure TNP Focus Group Meeting", European Tissue Repair Society, Proceedings, London, UK 232 pp. (2003). WFU-24	
7	BANWELL, P., et al., "Dermal perfusion in experimental partial thickness burns: the effect of topical subatmospheric pressure", January/February 2000, Burn Care & Rehabil., part 2, 21(1):S161, Proceedings of the American Burn Association, 32nd Annual Meeting, Las Vegas, Nevada (March 14-17, 2000). WFU-07	
8	BANWELL, P.E., et al., "Application of topical sub-atmospheric pressure modulates inflammatory cell extravasation in experimental partial thickness burns", Wound Repair and Regen., 7(4):A287 (July/August 1999). WFU-08	
9	DEFRANZO, A.J., et al., "109: Use of sub-atmospheric pressure for treatment of gunshot injuries", Plastic Surgical Forum, vol. XXIII, 69th Annual Scientific Meeting of the American Society of Plastic Surgeons, Los Angeles, CA, pp. 180-181 (1 sheet of abstract) (October 14-18, 2000). WFU-05	
10	DEFRANZO, A.J., et al., "The use of V.A.C. therapy for treatment of lower extremity wounds with exposed bone", 68th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, New Orleans, LA, pp. 37-38; 2 sheets of abstract (October 24-27, 1999). WFU-42	
11	KORTESIS, B., et al., "Vacuum-assisted closure for the treatment of open tibia fractures", 72nd Annual Meeting of the American Society of Plastic Surgeons, San Diego, CA, pp. 172-3; 1 sheet of abstract (October 25-29, 2003). WFU-41	

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KREMERS, L., et al., "Effect of topical sub-atmospheric pressure treatment on angiotensin I and II levels post burn". Sight Annual Meeting, Abstract printed in J. Burn Care Rehabilitation, page S44, Abstract no. 3 American Burn Association, Miami, Florida (April 1-4 2003). WFU-53 KREMERS, L., et al., "Serum interleukin levels post burn with and without application of sub-atmospheric pressure", 33th Annual Meeting, Abstract printed in Burn Care Rehabilitation, page S43, Abstract no. 2, American Burn Association, Miami, Florida, (April 1-4 2003). WFU-53 MARKS, M.W., et al., "Management of complex soft tissue defects in pediatric patients using the V.A.C. wound closure", Plastic Surgical Forum, vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, Boston, MA, pp. 215-216 (October 3-7, 1998). WFU-99 MOLNAR, J.A., et al., "Improved skin graft adherence and vascularization of integra(R) using subatmospheric pressure – a laboratory study", Abstract printed in Burn Care & Rehabilitation, page S111, Abstract no. 141; American Burn Meeting, 34th Annual Meeting, Chicago, IL., (April 24-27 2002). WFU-51 MORYKWAS, M., et al., "Treatment of burned extremities using vacuum therapy (The V.A.C.)", Wound Repair and Regeneration, 3(3):367, (Myl. September 1, 1995), Sth Annual Meeting of the European Tissue Society, Padova, Italy, (August 30 September 2, 1995). WFU-15 MORYKWAS, M.J., "The use of the V.A.C. wound treatment system for acute and subacute wounds", Plaies & Cicatrices, Would Closure Healing, European Master Class in Wound Closure and Healing, Montpellier, France, (3pp.) [MORYKWAS, M.J., et al., "Isoaled muscle flap survival with complete venous occusion, varying delay in external application of sub-ammospheric pressure." Plaistic Surgical Forum, Vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons Boston, MA, pp. 237 (Oct. 3-7, 1998). WFU-16 MORYKWAS, M.J., et al., "Sub-almospheric pressure to increase the rate of granulatio			
336th Annual Meeting, Abstract printed in Burn Care Rehabilitation, page S43, Abstract no. 2, American Burn Association, Miami, Florida, (April 1-4 2003). WFU-53	12	35th Annual Meeting, Abstract printed in J. Burn Care Rehabilitation, page S44, Abstract no. 3 American Burn	
14 closure", Plastic Surgical Forum, vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, Boston, MA, pp. 215-216 (October 3-7, 1998). WFU-09	13	35th Annual Meeting, Abstract printed in Burn Care Rehabilitation, page S43, Abstract no. 2, American Burn	
a laboratory study", Abstract printed in Burn Care & Rehabilitation, page \$111, Abstract no. 141; American Burn Meeting, 34th Annual Meeting, Chicago, IL., (April 24-27 2002). WFU-51 MORYKWAS, M., et al., "Treatment of burned extremities using vacuum therapy (The V.A.C.)", Wound Repair and Regeneration, 3(3):367, (July – September, 1995), 5th Annual Meeting of the European Tissue Society, Padova, Italy, (August 30-September 2, 1995). WFU-15 MORYKWAS, M.J., "The use of the V.A.C. wound treatment system for acute and subacute wounds", Plaies & Cicatrices, Would Closure Healing, European Master Class in Wound Closure and Healing, Montpellier, France, (3pp.) (April 21, 22 and 23, 1999). WFU-17 MORYKWAS, M.J., et al., "Isolated muscle flap survival with complete venous occlusion: varying delay in external application of sub-atmospheric pressure", Plastic Surgical Forum, Vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, Boston, MA, pp. 237 (Oct. 3-7, 1998). WFU-16 MORYKWAS, M.J., et al., "Sub-atmospheric pressure for the treatment of lower extremity wounds", The Third Riva Congress, Current Perspectives in Fracture Management and Orthopaedic Reconstruction, Riva del Garda, Italy, pp. 135-136, (May 10-14, 2000) WFU-18 MORYKWAS, M.J., et al., "Use of negative pressure to increase the rate of granulation tissue formation in chronic open wounds", FASEB J. part I, Abstracts 1-3006, (Extracellular Matrix and Healing, 799-800) (Feb. 19, 1993), Experimental Biology '93, abstract no. 800, New Orleans, Louisiana, (March 28-April 1, 1993). WFU-13 MORYKWAS, M.J., et al., "Use of negative pressure to prevent progression of partial thickness burns", American Burn Association, vol. 26, 26th Annual Meeting, Orlando, Florida, pp. 157 (April 20-23, 1994). WFU-14	14	closure", Plastic Surgical Forum, vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive	
Regeneration, 3(3):367, (July – September, 1995), 5th Annual Meeting of the European Tissue Society, Padova, Italy, (August 30-September 2, 1995). WFU-15 MORYKWAS, M.J., "The use of the V.A.C. wound treatment system for acute and subacute wounds", Plaies & Cicatrices, Would Closure Healing, European Master Class in Wound Closure and Healing, Montpellier, France, (3pp.) [MORYKWAS, M.J., et al., "Isolated muscle flap survival with complete venous occlusion: varying delay in external application of sub-atmospheric pressure", Plastic Surgical Forum, Vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, Boston, MA, pp. 237 (Oct. 3-7, 1998). WFU-16 MORYKWAS, M.J., et al., "Sub-atmospheric pressure for the treatment of lower extremity wounds", The Third Riva Congress, Current Perspectives in Fracture Management and Orthopaedic Reconstruction, Riva del Garda, Italy, pp. 135-136, (May 10-14, 2000) WFU-18 MORYKWAS, M.J., et al., "Use of negative pressure to increase the rate of granulation tissue formation in chronic open wounds", FASEB J. part I, Abstracts 1-3006, (Extracellular Matrix and Healing, 799-800) (Feb. 19, 1993), Experimental Biology '93, abstract no. 800, New Orleans, Louisiana, (March 28-April 1, 1993). WFU-13 MORYKWAS, M.J., et al., "Use of negative pressure to prevent progression of partial thickness burns", American Burn Association, vol. 26, 26th Annual Meeting, Orlando, Florida, pp. 157 (April 20-23, 1994). WFU-14	15	 a laboratory study", Abstract printed in Burn Care & Rehabilitation, page S111, Abstract no. 141; American Burn 	
17 Cicatrices, Would Closure Healing, European Master Class in Wound Closure and Healing, Montpellier, France, (3pp.)	16	Regeneration, 3(3):367, (July – September, 1995), 5th Annual Meeting of the European Tissue Society, Padova, Italy,	
application of sub-atmospheric pressure", Plastic Surgical Forum, Vol. XXI, 67th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, Boston, MA, pp. 237 (Oct. 3-7, 1998). WFU-16 MORYKWAS, M.J., et al., "Sub-atmospheric pressure for the treatment of lower extremity wounds", The Third Riva Congress, Current Perspectives in Fracture Management and Orthopaedic Reconstruction, Riva del Garda, Italy, pp. 135-136, (May 10-14, 2000) WFU-18 MORYKWAS, M.J., et al., "Use of negative pressure to increase the rate of granulation tissue formation in chronic open wounds", FASEB J. part I, Abstracts 1-3006, (Extracellular Matrix and Healing, 799-800) (Feb. 19, 1993), Experimental Biology '93, abstract no. 800, New Orleans, Louisiana, (March 28-April 1, 1993). WFU-13 MORYKWAS, M.J., et al., "Use of negative pressure to prevent progression of partial thickness burns", American Burn Association, vol. 26, 26th Annual Meeting, Orlando, Florida, pp. 157 (April 20-23, 1994). WFU-14	17	Cicatrices, Would Closure Healing, European Master Class in Wound Closure and Healing, Montpellier, France, (3pp.)	
Congress, Current Perspectives in Fracture Management and Orthopaedic Reconstruction, Riva del Garda, Italy, pp. 135-136, (May 10-14, 2000) WFU-18 MORYKWAS, M.J., et al., "Use of negative pressure to increase the rate of granulation tissue formation in chronic open wounds", FASEB J. part I, Abstracts 1-3006, (Extracellular Matrix and Healing, 799-800) (Feb. 19, 1993), Experimental Biology '93, abstract no. 800, New Orleans, Louisiana, (March 28-April 1, 1993). WFU-13 MORYKWAS, M.J., et al., "Use of negative pressure to prevent progression of partial thickness burns", American Burn Association, vol. 26, 26th Annual Meeting, Orlando, Florida, pp. 157 (April 20-23, 1994). WFU-14	18	application of sub-atmospheric pressure", Plastic Surgical Forum, Vol. XXI, 67th Annual Meeting of the American	
open wounds", FASEB J. part I, Abstracts 1-3006, (Extracellular Matrix and Healing, 799-800) (Feb. 19, 1993), Experimental Biology '93, abstract no. 800, New Orleans, Louisiana, (March 28-April 1, 1993). WFU-13 MORYKWAS, M.J., et al., "Use of negative pressure to prevent progression of partial thickness burns", American Burn Association, vol. 26, 26th Annual Meeting, Orlando, Florida, pp. 157 (April 20-23, 1994). WFU-14	19	Congress, Current Perspectives in Fracture Management and Orthopaedic Reconstruction, Riva del Garda, Italy, pp.	
Association, vol. 26, 26th Annual Meeting, Orlando, Florida, pp. 157 (April 20-23, 1994). WFU-14 MORYKWAS, M.J., et al., "V.A.C. experience and difficult wounds," des Journees Regionales des Plaies et	20	open wounds", FASEB J. part I, Abstracts 1-3006, (Extracellular Matrix and Healing, 799-800) (Feb. 19, 1993),	
	21		
	22		

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	23	MORYKWAS, M.J., et al., "Negative pressure treatment of burned extremities", 65th Annual Scientific Meeting, American Society of Plastic and Reconstructive Surgeons, Dallas, TX, pp. 86-87; 1 sheet of abstract (November 9-13, 1996). WFU-36				
	24	MORYKWAS, M.J., et al., "The effect of V.A.C.(TM) therapy on the length of stay, total charges and average daily charge for patients assigned to DRG 263: analysis of 13 consecutive quarters", presented in part at the 28th Annual Conference of the Wound, Ostomy, and Continence Nurses Society, Seattle, WA, (15 sheets) (June 15-19, 1996). WFU-52				
	25	PARK, C.A., et al., "Outpatient use of Integra® and subatmospheric pressure in the management of wound and burn reconstruction", J. Burn Care Rehabil., 26(2 suppl.):S113, Chicago, IL, (May 10-13, 2005). WFU-62				
	26	SCHNEIDER, A.M., et al., "Muscle flap survival after complete venous occlusion by application of a negative pressure device", 66th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, San Francisco, CA, pp. 300-302; 2 sheets of abstract (September 21-24 1997). WFU-38				
	27	SCHNEIDER, A.M., et al., "Treatment of brown recluse spider bite wounds by external application of sub-atmospheric pressure", 68th Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, New Orleans, LA, page 35; 1 sheet of abstract (October 24-27, 1999). WFU-40				
	28	WEBB, L.X., "Use of negative pressure devices in highly contaminated, high energy wounds", Extremity War Injuries: State of the Art and Future Directions, AAOS/OTA Extremity War Injures Symposium, January 24-27, 2006, [Abstract]. WFU-65				
	29	WEBB, L.X., et al., "Negative pressure wound therapy in the management of orthopedic wounds", Ostomy Wound Management, 50(4A Suppl.):26-27, Supplement - Proceedings from the 2003 National V.A.C.™ Education Conference (April 2004). WFU-22				
	30	WEBB, L.X., et al., "The use of vacuum-assisted closure in composite wound management", The Third Riva Congress, Current Perspectives in Fracture Management and Orthopaedic Reconstruction, Riva del Garda, Italy, pp. 137 (May 10-14, 2000). WFU-20				
	31	MORYKWAS, M.J., "Basic Research and Animal Studies," Presentation at the European Topical Negative Pressure Meeting in Salsbury, England, (June 2005). WFU-71				
	32	DEFRANZO, A.J., et al., "Vacuum assisted closure of the abdominal wall", 73rd Annual Meeting, American Association of Plastic Surgeons, Philadelphia, PA (2004), 1 sheet of abstract. WFU-60				
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